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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,613	08/04/2000	Holly Hogrefe	04121.0116-07000	6689
27495 7590 03/28/2008 AGILENT TECHNOLOGIES INC P.O BOX 7599 BLDG E , LEGAL LOVELAND, CO 80537-0599				
EXAMINER				
WILDER, CYNTHIA B				
ART UNIT		PAPER NUMBER		
1637				
NOTIFICATION DATE		DELIVERY MODE		
03/28/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

09/631,613

**Applicant(s)**

HOGREFE ET AL.

**Examiner**

CYNTHIA B. WILDER

**Art Unit**

1637

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 69, 70 and 72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69, 70, 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment after-final filed on 1/22/2008 is acknowledged and has been entered. Claims 1-68, 71, 73 and 75-94 have been canceled. Claims 69 and 72 have been amended. Claims 69, 70, 72 and 74 are pending. Finality of the previous Office action is withdrawn to address the new grounds of rejections presented in this Office action.

#### ***Sequence Listing***

2. This application contains sequence disclosure that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice to Comply with Requirements for Patent Applications containing Nucleotide Sequence and/or Amino acid Sequence Disclosures. Specifically, the specification contain sequences, SEQ ID NOS: 62-89 that are not contained in the raw sequence listing or computer readable form (see attached notice to comply).

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 69-70 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of "a sequence encoding polymerase enhancing factor protein 45" and "a polymerase enhancing factor activity" is not adequately described in the instant invention such that one of skilled in the art would clearly know what sequences are needed for the instant method to operate. The specification teaches that the polymerase enhancing factor requires P45 and P50 proteins and teaches these sequences in SEQ ID NOS: 9-13 (page 30). The specification teaches multiple sequences that represents a consensus uridine binding sequence (SEQ ID NO: 72-81). The specification teaches that these sequences may be used as a polymerase enhancing activity or polymerase enhancing factor (PEF) (page 44). Neither the specification nor claims clearly identifies what sequences actually represents a polymerase enhancing factor versus a polymerase enhancing factor activity versus a polymerase enhancing factor protein 45. It cannot be determined from the specification or claims what sequences are necessary for the method to operate in order to enhance a nucleic acid polymerase reaction and/or what sequences actually defines the terms as used in the claim. Further, the recitation of a "p45 protein", "a sequence enhancing factor 45" and "a polymerase enhancing factor protein activity" encompasses a large species of nucleic acid species that are not adequately described or disclosed in the instant specification.

A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the "written description inquiry, *whatever is now claimed* (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceuticals Co. LTd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to a lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d1398, 1404, 1405 held:

....To fulfill the written description requirements, a patent specification must describe an invention and do so in sufficient details that one skill in the art can clearly conclude that "the invention invented the claimed invention". Lockwood v. American Airlines, Inc. 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed". Thus, an Applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious", and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Due to the lack of adequate written description in this case, one of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus.

***Conclusion***

5. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/cbw/  
/Gary Benzion/  
Supervisory Patent Examiner, Art Unit 1637